Claims

1. Controlled-release pharmaceutical composition with gastric residence, characterized in that it comprises two or three layers and in that it comprises:

(a) an active principle combined with an excipient which modifies its release,

(b) a carbon dioxide-generating system in a swelling hydrophilic polymer matrix,

(a) and (b) possibly being included in the same layer [(a)+(b)] or in separate layers [(a)] and [(b)] and the redundant layers [(a)], [(b)] or [(a)+(b)] in the same tablet possibly having different compositions and dimensions.

2. Composition according to Claim 1, characterized in that the swelling polymer matrix consists of a hydrophilic polymer which may be chosen from the following families of hydrophilic polymers:

- natural polysaccharides,
- cellulose derivatives,
- polyvinylpyrrolidones,
- polymers derived from acrylic acid and methacrylic acid and salts thereof,
- aminoacid polymers,

or from a mixture of 2 or 3 of them, chosen from the same family of hydrophilic polymers.

3. Composition according to Claim 2,

characterized in that the hydrophilic polymers may be chosen from:

- alginates, xanthan gum, guar gum, gum arabic or carob gum,
- methylhydroxyethylcellulose, carboxymethylcellulose, sodium carboxymethylcellulose or calcium carboxymethylcellulose, hydroxypropylcellulose or hydroxypropylmethylcellulose,
- polyacrylates, or
- polylysines.

4. Composition according to any one of Claims 1 to 3, characterized in that it also comprises a hydrophilic excipient capable of promoting the hydration of swelling polymer matrices, chosen from lactose, mannitol, sorbitol, microcrystalline cellulose, sodium lauryl sulfate, sodium ricinoleate, sodium tetradecyl sulfate, sodium dioctyl sulfosulfonate, ketomagrocol, poloxamer and polysorbates.

5. Composition according to any one of Claims 1 to 4, characterized in that the excipient which modifies the release of the active principle may be chosen from the hydrophilic polymers according to Claim 2 or 3 or from ethylcellulose, methylcellulose and acrylic copolymers,

and also, when (a) and (b), as defined in Claim 1, are in separate layers, also from lipid substances such as

hydrogenated castor oil, beeswax, carnauba wax, glyceryl trimyristate, glyceryl trilaurate, glyceryl tristearate, cetyl palmitate and glyceryl behenate, or a combination of a hydrophilic polymer and a lipid substance.

6. Composition according to any one of Claims 1 to 5, characterized in that the carbon dioxide-generating system comprises at least one carbon dioxide-generating agent which may be chosen from an alkali metal carbonate or alkaline-earth metal carbonate, such as calcium carbonate, and an alkali metal bicarbonate, such as sodium bicarbonate.

7. Composition according to Claim 6, characterized in that the carbon dioxide-generating system comprises at least one carbon dioxide-generating agent and at least one acidic compound chosen from the group consisting of monocarboxylic acids, polycarboxylic acids and partial salts of polycarboxylic acids.

8. Composition according to either of Claims 6 and 7, characterized in that the acidic compound is tartaric acid, succinic acid, citric acid or a partial salt thereof, such as monosodium citrate.

9. Composition according to any one of Claims 1 to 8, characterized in that the active principle is a benzamide, such as metoclopramide, veralipride, alizapride, clebopride, amisulpride,

tiapride or sulpiride, in the form of an enantiomer, diastereoisomers or a mixture, in particular a racemic mixture, or a salt thereof.

10. Composition according to Claim 9, characterized in that the benzamide is amisulpride (D)-tartrate, (S)-(-)-amisulpride, (S)-(-)-amisulpride (D)-tartrate or tiapride hydrochloride.

11. Composition according to one of Claims 1 to 8, characterized in that the active principle is an α_1-antagonist such as terazosine or alfuzosine in the form of an enantiomer, a diastereoisomer or a mixture, in particular a racemic mixture, or a salt thereof, in particular alfuzosine hydrochloride.

12. Composition according to one of Claims 1 to 8, characterized in that the active principle is captopril, furosemide, ursodeoxycholic acid or amoxicillin, (+)-α-aminomethyl-2-methoxy-5-sulfonamidobenzenemethanol or 3'-(2-amino-1-hydroxyethyl)-4'-fluoromethanesulfonanilide, or a salt thereof.

13. Composition according to Claim 12, characterized in that the active principle is 3'-(2-amino-1-hydroxyethyl)-4'-fluoromethane-sulfonanilide hydrochloride.